

EPA REGISTRATION NUMBER 89459-16 – VOL. 2

PROCESSING REQUEST

Reg # 89459-16

Decision # 513826

Description: Revise Basic CSF

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 9-16-15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 3-17-16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 18, 2016

Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet Company
1501 East Woodfield Road, Suite 200W
Schaumburg, IL 60173

Subject: CSF Notification per PRN 98-10 –Revising Basic CSF
Product Name: PRENTOX 20% PYRETHRUM EXTRACT
EPA Registration Number: 89459-16
Application Date: 2/5/2016
Decision Number: 513828

Dear Ms. Hood:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 9/16/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Angela Hollis at 703-347-0216 or by email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch I
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Central Garden & Pet Company/89459-16	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Central Garden & Pet Company/Prentox 20% Pyrethrum Extract	PM # 3	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Central Garden & Pet Company 1501 East Woodfield Road, Suite 200W Schaumburg, IL 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

Section - II

- ☐ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☒ Notification - Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
- ☐ "Me Too" Application
- ☐ Other - Explain below.

NOTIFICATION

MAR 18 2016

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Notification of alternate source of active ingredient. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. For questions, please contact Kristin Hood, Tel: 847-330-5360; E-Mail: khood@central.com

Section - III

1. Material This Product Will be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Unit Packaging wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 & 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kristin Hood	Title Regulatory Affairs Specialist	Telephone No. (include Area Code) 847-330-5360
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Kristin Hood	5. Date February 5, 2016	



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Central Garden & Pet Company 1501 E. Woodfield Rd., Suite 200W Schaumburg, IL 60173	EPA File Symbol/Registration Number 89459-16
	Product Name Prentox 20% Pyrethrum Extract
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09/16/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Pyrethrins CAS# 8003-34-7

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Pyrethrins		
Product ingredient source information may be entitled to confidential treatment		
Signature 	Name and Title Kristin Hood Regulatory Affairs Specialist	Date 02/05/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy



Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet Company
1501 E. Woodfield Rd
Suite 200W
Schaumburg, IL 60173

847-330-5360 phone
847-330-5391 fax

khood@cgpcentral.com

February 5, 2016

Document Processing Desk (NOTIF)
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Bo Davis
Product Manager 3

Subject: NOTIFICATION OF ALTERNATE SOURCES OF ACTIVE INGREDIENT
Prentox 20% Pyrethrum Extract; EPA Reg. No. 89459-16

Dear Mr. Davis,

This submission is a follow-up to the discussion between you and Steve Spaulding on February 4, 2016 regarding the most recent submission on this subject from September 16, 2016. This discussion pertains to the addition of the following two alternate sources of [REDACTED] Pyrethrins to the Prentox 20% Pyrethrum Extract CSF.

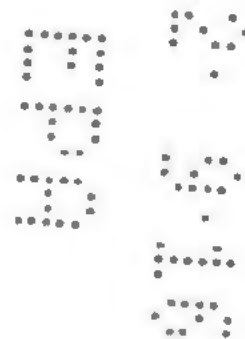
- 1) [REDACTED]
- 2) [REDACTED]

The [REDACTED] Pyrethrin sources have more uses on the labels than the Prentox 20% Pyrethrum Extract and therefore, a data matrix is not required.

Enclosed, please find a notification of additional sources of active ingredient for Prentox 20% Pyrethrum Extract.

The following materials are enclosed:

- 1) Application for Pesticide Registration Notification
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula



Product ingredient source information may be entitled to confidential treatment

If you have any questions, please do not hesitate to contact me at (847) 330-5360 or through email at khoo@central.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Kristin Hood". The signature is fluid and cursive, with the first name "Kristin" and last name "Hood" clearly distinguishable.

Kristin Hood
Regulatory Affairs Specialist

Enclosures

2025



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 30, 2015

Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet Company
1501 East Woodfield Road, Suite 200W
Schaumburg, IL 60173

Subject: Notification per PRN 98-10 – notification to add two alternate a.i. sources
Product Name: PRENTOX 20% PYRETHRUM EXTRACT
EPA Registration Number: 89459-16
Application Date: 9/16/2015
Decision Number: 509364

Dear Ms. Hood:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the request is not acceptable for the following reasons:

1. This action requires a data matrix listing out all of the required guidelines and MRIDs the additional use.

No further processing of this application will occur. You may submit a new application addressing the deficiencies listed above for future consideration. Our records have been updated accordingly to note that this notification is unacceptable.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within an oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet Company
1501 E. Woodfield Rd
Suite 200W
Schaumburg, IL 60173

847-330-5360 phone
847-330-5391 fax

khoo@central.com

September 16, 2015

Document Processing Desk (NOTIF)
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Bo Davis
Product Manager 3

Subject: NOTIFICATION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT
Pretox 20% Pyrethrum Extract; EPA Reg. No. 89459-16

Dear Mr. Davis,

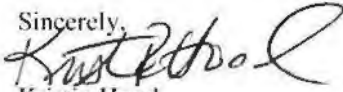
Enclosed, please find a notification of additional source of active ingredient for the above subject product.

This product is being submitted per PR Notice 98-10. The alternate source of active ingredient is not registered for residential uses, however Central Garden & Pet Company (and its affiliates) are a member of the ORETF, NDETF, & REJV. We believe the data submitted by these task forces fulfill the data for residential exposure as noted on the source product label and that this notification is consistent with 40 CFR 152.46.

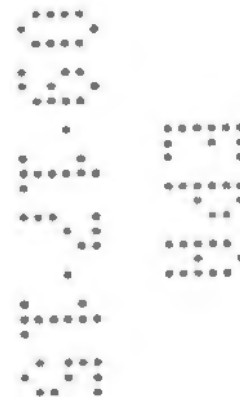
The following materials are enclosed:

- 1) Application for Pesticide Registration Notification
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula
- 4) Letters demonstrating membership in ORETF, NDETF, & REJV.

If you have any questions, please do not hesitate to contact me at (847) 330-5360.

Sincerely,

Kristin Hood
Regulatory Affairs Specialist

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Central Garden & Pet Company/89459-16	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Central Garden & Pet Company/Prentox 20% Pyrethrum Extract	PM # 3	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Central Garden & Pet Company 1501 East Woodfield Road, Suite 200W Schaumburg, IL 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Notification of alternate source of active ingredient. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. For questions, please contact Kristin Hood, Tel: 847-330-5360; E-Mail: khood@central.com

Section - III

1. Material This Product Will be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Unit Packaging wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 & 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kristin Hood	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 847-330-5380
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Kristin Hood	5. Date September 16, 2015	



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Central Garden & Pet Company 1501 E. Woodfield Rd., Suite 200W Schaumburg, IL 60173	EPA File Symbol/Registration Number 89459-16
	Product Name Prentox 20% Pyrethrum Extract
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09/16/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Pyrethrins CAS# 8003-34-7

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Pyrethrins		
Product ingredient source information may be entitled to confidential treatment		
Signature 	Name and Title Kristin Hood Regulatory Affairs Specialist	Date 09/16/2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Kristin Hood

From: Rudick, Maggie [Rudick.Maggie@epa.gov]
Sent: Wednesday, September 16, 2015 9:55 AM
To: Kristin Hood
Cc: Steve Spaulding
Subject: RE: Agency Letter - EPA Reg # 89459-16

Kristin –

I am not sure if I am understanding your question correctly. You had requested to add 3 new suppliers via notification – the [REDACTED]

Looking over these again, it looks like We could approve the [REDACTED] suppliers. If you wanted to resubmit an alternate CSF adding just these 2 suppliers, we should be able to approve the CSF notification. Please include a copy of this email in your submission in case this is assigned to another reviewer.

Thank you,

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
(703) 347-0257
Rudick.Maggie@epa.gov

From: Kristin Hood [mailto:khoo@central.com]
Sent: Tuesday, September 15, 2015 4:42 PM
To: Rudick, Maggie
Cc: Steve Spaulding
Subject: RE: Agency Letter - EPA Reg # 89459-16

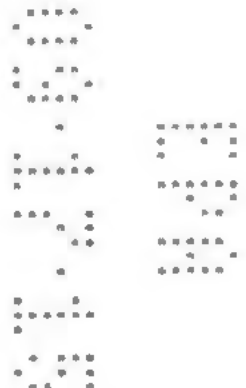
Ms. Rudick,

We understand that the [REDACTED] label is going through reregistration and so we will not add that as an alternate source at this time.

In comparing the [REDACTED] label with our label, we don't have aquatic food use. Do we have to submit a data matrix to add aquatic food use or, if we don't want aquatic food use, do we have to add that as a restriction on the label? Do you have any suggestions?

Thank you,

Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet
(847) 330-5360 (ph)
(847) 330-5391 (fx)
khoo@central.com



From: Rudick, Maggie [mailto:Rudick.Maggie@epa.gov]
Sent: Wednesday, September 09, 2015 1:07 PM
To: Kristin Hood
Subject: RE: Agency Letter - EPA Reg # 89459-16

Kristin –

The language “*this product may be used to formulate products for specific uses not listed on manufacturing product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such uses.*” was originally developed by EPA to make clear that even if the source product is not registered/supported for a given use, the formulator lawfully can still add that use to its label if it complies with data submission/data compensation obligations (see PR Notices 91-8 & 94-1).

So if you want an additional use it would need to meet the requirements of 152.80-.99 (the data comp regs) to address any data requirements that apply to the additional uses – meaning you must submit or cite data under either the selective or cite-all methods of support. If you are a task force member, then, for the relevant data, I assume you would assert in the data matrix that you have permission to cite such data.

Please let me know if that addresses Central’s question about why we had to turn down these notifications.

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
[\(703\) 347-0257](tel:(703)347-0257)
Rudick.Maggie@epa.gov

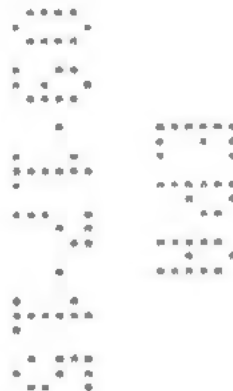
From: Rudick, Maggie
Sent: Wednesday, August 19, 2015 11:44 AM
To: 'Kristin Hood'
Subject: RE: Agency Letter - EPA Reg # 89459-16

Kristin –

Product ingredient source information may be entitled to confidential treatment

EPA Reg #s [REDACTED]

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
[\(703\) 347-0257](tel:(703)347-0257)
Rudick.Maggie@epa.gov



From: Kristin Hood [mailto:khoo@central.com]
Sent: Wednesday, August 19, 2015 11:17 AM
To: Rudick, Maggie
Subject: RE: Agency Letter - EPA Reg # 89459-16

Ms. Rudick,

Which two technical sources do not address uses on the label?

Thank you,

Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet
(847) 330-5360 (ph)
(847) 330-5391 (fx)
khoo@central.com

From: Rudick, Maggie [mailto:Rudick.Maggie@epa.gov]
Sent: Wednesday, August 19, 2015 9:59 AM
To: Kristin Hood
Subject: Agency Letter - EPA Reg # 89459-16

Ms. Hood –

After reviewing your submitted CSF notification for EPA Reg # 89459-16, it was determined that the revised basic CSF is not acceptable. Please see attached Agency letter for details and feel free to contact me if you have additional questions.

Maggie Rudick
U. S. Environmental Protection Agency
Office of Pesticides Program
Registration Division; Invertebrate & Vertebrate Branch I
(703) 347-0257
Rudick.Maggie@epa.gov

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Disclaimer: This communication and any attachments contain private, confidential, privileged and/or proprietary information intended solely for the Recipient(s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize and ask that you please notify the Sender by returning this e-mail and permanently deleting this communication from your computer, including destruction of any printed copies. Any views expressed herein are not necessarily those of the Company represented by this e-mail source. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication.



Representing Household & Institutional Products

Aerosol • Air Care • Cleaners • Polishes
Automotive Care • Antimicrobial • Pest Management

September 9, 2014

Mr. Steven R. Spaulding
Senior Director of Regulatory Affairs
Central Garden & Pet
1340 Treat Boulevard,
Suite 600
Walnut Creek, CA 94597

Re: NDETF Member in Good Standing

Dear Mr. Spaulding:

This is to certify that Central Garden & Pet ("Central") is a member in good standing of the Non-Dietary Exposure Task Force (NDETF), and, as such, Central and its affiliates have the right to cite and/or rely on all data submitted by the NDETF.

If you have any questions, please do not hesitate to contact me directly at (202) 833-7315.

Sincerely,

A handwritten signature in cursive script that reads "Susan L. Little".

Susan Little
Executive Director, PIR Program
Consumer Specialty Products Association, Inc.



Representing Household & Institutional Products

Aerosol • Air Care • Cleaners • Polishes
Automotive Care • Antimicrobials • Pest Management

September 10, 2014

Dr. James McFadden
Central Life Sciences
1501 East Woodfield Rd, Suite 200 W
Schaumburg, IL 60173

Re: REJV Member in Good Standing

Dear Dr. McFadden:

This is to certify that Central Life Sciences is a member in good standing of the Residential Exposure Joint Venture (REJV), company number 74888, and, as such, has the right to cite and/or rely on all data submitted by the REJV for purposes of responding to U.S. EPA's GDCI dated January 12, 2012, for pyrethrins and pyrethroid use and usage information.

If you have any questions, please do not hesitate to contact me directly at (202) 833-7315.

Sincerely,

Susan Little
Executive Director, PIR Program
Consumer Specialty Products Association, Inc.

OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE

*David R. Johnson, Ph.D.
ORETF Manager
Johnson Management & Consulting, LLC
Tel (660) 395-9590
Fax (660) 395-9593
davejohn@johnsonmgt.com*

October 16, 2014

U. S. Environmental Protection Agency
2777 South Crystal Drive
Arlington, VA 22202

Subject: Use of Outdoor Residential Exposure Task Force data by EPA for Central Garden & Pet Company registrations

To Whom it Concern:

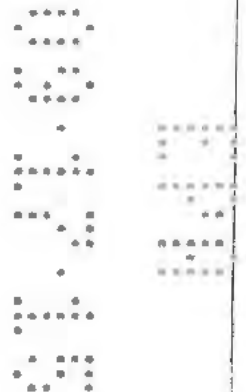
I am writing this letter as Manager of the Outdoor Residential Exposure Task Force (ORETF). The purpose for this letter is to confirm that EPA is authorized to use data submitted by the ORETF to support Central Garden & Pet Company registrations.

I will be pleased to respond to any questions EPA representatives may have regarding the use of ORETF data for Central Garden & Pet Company.

Regards,



David R. Johnson
ORETF Manager on behalf of
Jeffrey D. Burkey, ORETF Administrative Committee Chair





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 19, 2015

Kristin Hood
Central Garden & Pet Company
1501 East Woodfield Road, Suite 200W
Schaumburg, IL 60173

Subject: Notification per PRN 98-10 – Unacceptable Alternate Suppliers
Product Name: PRENTOX 20% PYRETHRUM EXTRACT
EPA Registration Number: 89459-16
Application Date: July 1, 2015
Decision Number: 506632

Dear Ms. Hood:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the request is not acceptable for the following reason:

Two of the technical sources on your proposed Basic Formulation dated 07/01/15 do not specifically address uses on your label. These uses must be listed on the technical source labels in order for you to be able to formulate from them.

No further processing of this application will occur. You may submit a new application addressing the deficiencies listed above for future consideration. Our records have been updated accordingly to note that this notification is unacceptable.

If you have any questions, you may contact Maggie Rudick at (703) 347-0257 or via email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Maggie Rudick" with "for" written below it.

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet Company
1501 E. Woodfield Rd
Suite 200W
Schaumburg, IL 60173
847-330-5360 phone
847-330-5391 fax
khoo@central.com

July 1, 2015

Document Processing Desk (NOTIF)
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Bo Davis
Product Manager 3

Subject: NOTIFICATION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT
Prentox 20% Pyrethrum Extract; EPA Reg. No. 89459-16

Dear Mr. Davis,


Enclosed, please find a notification of additional source of active ingredient for the above subject product.

This product is being submitted per PR Notice 98-10. The alternate source of active ingredient is not registered for residential uses, however Central Garden & Pet Company (and its affiliates) are a member of the ORETF, NDETF, & REJV. We believe the data submitted by these task forces fulfill the data for residential exposure as noted on the source product label and that this notification is consistent with 40 CFR 152.46.

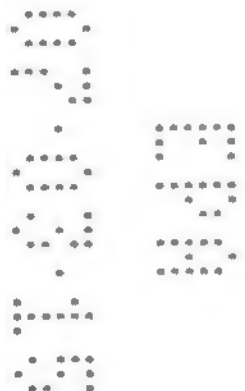
The following materials are enclosed:

- 1) Application for Pesticide Registration Notification
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula
- 4) Letters demonstrating membership in ORETF, NDETF, & REJV.

If you have any questions, please do not hesitate to contact me at (847) 330-5360.

Sincerely,

Kristin Hood
Regulatory Affairs Specialist

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Central Garden & Pet Company/89459-16	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Central Garden & Pet Company/Prentox 20% Pyrethrum Extract	PM # 3	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Central Garden & Pet Company 1501 East Woodfield Road, Suite 200W Schaumburg, IL 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Notification of alternate source of active ingredient. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. For questions, please contact Kristin Hood, Tel: 847-330-5360; E-Mail: khood@central.com

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Unit Packaging wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 & 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point: (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kristin Hood	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 847-330-5380
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Kristin Hood	5. Date July 1, 2015	



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Central Garden & Pet Company 1501 E. Woodfield Rd., Suite 200W Schaumburg, IL 60173	EPA File Symbol/Registration Number 89459-16
	Product Name Prentox 20% Pyrethrum Extract
	Date of Confidential Statement of Formula (EPA Form 8570-4) 07/01/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Pyrethrins CAS# 8003-34-7

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

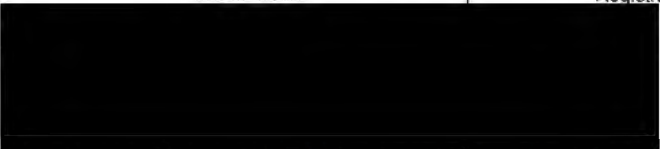

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Pyrethrins		
Product ingredient source information may be entitled to confidential treatment		
Signature 	Name and Title Kristin Hood Regulatory Affairs Specialist	Date 07/01/2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy



Representing Household & Institutional Products

Aerosol • Air Care • Cleaners • Polishes
Automotive Care • Antimicrobial • Pest Management

September 9, 2014

Mr. Steven R. Spaulding
Senior Director of Regulatory Affairs
Central Garden & Pet
1340 Treat Boulevard,
Suite 600
Walnut Creek, CA 94597

Re: NDETF Member in Good Standing

Dear Mr. Spaulding:

This is to certify that Central Garden & Pet ("Central") is a member in good standing of the Non-Dietary Exposure Task Force (NDETF), and, as such, Central and its affiliates have the right to cite and/or rely on all data submitted by the NDETF.

If you have any questions, please do not hesitate to contact me directly at (202) 833-7315.

Sincerely,

A handwritten signature in cursive script that reads "Susan Little".

Susan Little
Executive Director, PIR Program
Consumer Specialty Products Association, Inc.



September 10, 2014

Dr. James McFadden
Central Life Sciences
1501 East Woodfield Rd, Suite 200 W
Schaumburg, IL 60173

Re: REJV Member in Good Standing

Dear Dr. McFadden:

This is to certify that Central Life Sciences is a member in good standing of the Residential Exposure Joint Venture (REJV), company number 74888, and, as such, has the right to cite and/or rely on all data submitted by the REJV for purposes of responding to U.S. EPA's GDCI dated January 12, 2012, for pyrethrins and pyrethroid use and usage information.

If you have any questions, please do not hesitate to contact me directly at (202) 833-7315.

Sincerely,

Susan Little
Executive Director, PIR Program
Consumer Specialty Products Association, Inc.

EPA
OUTDOOR RESIDENTIAL EXPOSURE
TASK FORCE

David R. Johnson, Ph.D.
ORETF Manager
Johnson Management & Consulting, LLC
Tel (660) 395-9590
Fax (660) 395-9593
davejohn@johnsonmgt.com

07.03.15

October 16, 2014

U. S. Environmental Protection Agency
2777 South Crystal Drive
Arlington, VA 22202

Subject: Use of Outdoor Residential Exposure Task Force data by EPA for Central Garden & Pet Company registrations

To Whom it Concerns:

I am writing this letter as Manager of the Outdoor Residential Exposure Task Force (ORETF). The purpose for this letter is to confirm that EPA is authorized to use data submitted by the ORETF to support Central Garden & Pet Company registrations.

I will be pleased to respond to any questions EPA representatives may have regarding the use of ORETF data for Central Garden & Pet Company.

Regards,



David R. Johnson
ORETF Manager on behalf of
Jeffrey D. Burkey, ORETF Administrative Committee Chair



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 20, 2015

Kristin Hood
Regulatory Affairs Specialist
Central Garden & Pet Company
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173

Subject: Label Notification per PRNs 98-10 and 2007-4 – Updated container handling
language and other minor revisions
Product Name: Prentox 20% Pyrethrum Extract
EPA Registration Number: 89459-16
Application Date: March 4, 2015
Decision Number: 501365

Dear Ms. Hood:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notices (PRNs) 98-10 and 2007-4 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRNs 98-10 and 2007-4 and finds that the actions requested fall within the scope of PRNs 98-10 and 2007-4.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification via PR Notice 98-10) or durably marked on the container itself.

If you have any questions, you may contact Julie Chao at (703) 308-8735 or via email at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", with a small square mark to the right.

Kable Bo Davis, Product Manager 03
Invertebrate & Vertebrate Branch I
Registration Division (7505P)
Office of Pesticide Programs



20% PYRETHRUM EXTRACT
An insecticide for formulating use only.

ACTIVE INGREDIENT:

Pyrethrins..... 20.00%

OTHER INGREDIENTS*±: 80.00%

TOTAL 100.00%

*±Contains Petroleum Distillates

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. ~~655-7589459-16~~

EPA Est. No.

NOTIFICATION

89459-16

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated

3/20/2015

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

User Safety Recommendations:

- User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye.• Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Immediately call a Poison Control Center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a Poison Control Center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-248-7763 222-1222 for emergency medical treatment information. You may also contact the National Pesticide Telecommunication Network at 1-800-858-7378 for information including health concerns, medical emergencies or pesticide incidents.	
NOTE TO PHYSICIAN: Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into insecticides for the following uses: Terrestrial Food/Feed and Non-Food Crops, Aquatic Non-Food, Greenhouse Food and Non-food, Domestic Indoor and Outdoor, Indoor Food and Non-Food.

Not for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end-use products.

Formulated pet spray products must not contain more than 0.2% pyrethrins.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: If container is damaged. Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of wastes as below. Do not store, use, pour, or spill near heat or open flame. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. **{For containers 5 gallons or less}** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available or reconditioning, if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. **{For containers greater than 5 gallons}** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or reconditioning, if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PRENTOX[®] is a registered trademark of Wellmark International ~~Prentiss Incorporated~~

Manufactured by for:

~~PRENTISS LLC~~

~~2155 West Croft Circle~~

~~Spartanburg, SC 29302~~

Central Garden & Pet Company

1501 East Woodfield Road 200W

Schaumburg, IL 60173



United States
Environmental Protection Agency
Washington, DC 20460

☐ Re
☐ Amend
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Central Garden & Pet Company/89459-16	2. EPA Product Manager S. Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Central Garden & Pet Company/Prentox 20% Pyrethrum Extract	PM # 20	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Central Garden & Pet Company 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Label Notification per PRN 2007-4 to revise Storage and Disposal/Container handling. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. For questions, please contact Kristin Hood, Tel: 847-330-5360; E-Mail: khood@central.com

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted If "Yes" Unit Packaging wgt. No. per container If "Yes" Unit Packaging wgt. No. per container					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 gal./210 lb./375 lb.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kristin Hood	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) (847) 330-5360
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Kristin Hood	5. Date 04-Mar-15	



March 4, 2015

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: S. Joyner, PM 20

SUBJECT: NOTIFICATION PER PRN 2007-4/CONTAINER DISPOSAL
FOR Pretox 20% Pyrethrum Extract/EPA REG. NO. 89459-16

Dear Ms. Joyner:

Enclosed is a completed EPA form 8570-1 and 1 copy of revised labeling for the above product plus one clean copy to serve as notification per PRN 2007-4. The added text represents exact wording from the regulations/PR Notice and other minor changes were made to the label. This action is not a PRIA action and does not require any fee.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5360. Thank you for your assistance in this matter.

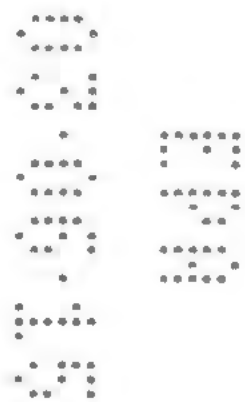
Yours sincerely,
CENTRAL GARDEN & PET COMPANY

A handwritten signature in black ink, appearing to read "Kristin Hood".

Kristin Hood
Regulatory Affairs Specialist
khoo@central.com

enclosure

cc: C. Elmi

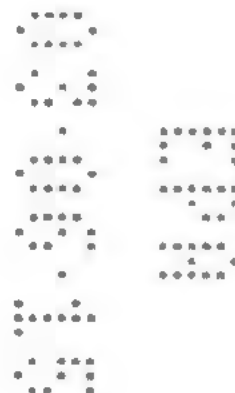


REGULATORY LABEL DATA SHEET

File Name:	Epa notif add rinse 315	Data Sheet Date:	March 2015
Product:	Prentox 20% Pyrethrum Extract	EPA Reg #:	89459-16 (was 655-75)
Approved:		Supersedes:	5-9-13

OVERVIEW: Label notification per PRN 2007-4 to revise Storage and Disposal/Container Handling (add rinse DFU). Exact text from PR Notice was used.

Page #	Description of Major Changes
1	Ingredient Statement: deleted extra asterisk Deleted zeroes in percentages, not needed Reference statement, deleted "side panel for", only one pg label EPA Reg No: revised to reflect 11/16/14 transfer from Prentiss to Central Garden Pet Company
2	First Aid – revised telephone number to CGP brand number
3	Storage/Disposal: per PRN 2007-4 (exact text), revised Container Handling to include triple rinse DFU
4	Revised trademark statement Revised registrant name/address to CGP





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 16, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. STEVEN R. SPAULDING
CENTRAL GARDEN & PET COMPANY
1501 EAST WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Dear Mr. Spaulding:

Subject: Transfer of Pesticide Registrations and Data From Company Number 655 to
Company Number 89459

Pursuant to your request in your letter and transfer agreement of June 04, 2014, we
have approved the transfer of the following registrations from **PRENTISS LLC**, company
number **655** to **CENTRAL GARDEN & PET COMPANY**, company number **89459**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
PRENTOX CUBE POWDER	655-3	89459-13
PRENTOX PYRONYL 50-5 OIL CONCENTRATE	655-52	89459-14
PRENTOX CUBE RESINS	655-69	89459-15
PRENTOX 20% PYRETHRUM EXTRACT	655-75	89459-16
PRENTOX PYRONYL 75	655-87	89459-17
PRENTOX PYRONYL 60-6 EMULSIFIABLE CONCENTRATE	655-90	89459-18
PRENTOX PIPERONYL BUTOXIDE TECHNICAL	655-113	89459-19
PRENTOX PYRONYL 9 18-30	655-128	89459-20
PRENTOX PYRONYL 6-15-15	655-316	89459-21
PRENTOX PYRETHRUM CRUDE EXTRACT	655-407	89459-22
PRENTOX PRENFISH TOXICANT	655-422	89459-23
PRENTOX PYRONYL OIL CONCENTRATE #525	655-471	89459-24
PRENTOX PYRETHRUM EXTRACT	655-486	89459-25
PRENTOX PYRONYL CROP SPRAY	655-489	89459-26
PRENTOX PYRONYL OIL CONCENTRATE OR-3610A	655-501	89459-27

PRENTOX PRENBAY 1% OIL SOLUTION	655-546	89459-28
PRENTOX EMULSIFIABLE SPRAY CONCENTRATE #96	655-587	89459-29
PRENTOX FOGGING INSECTICIDE PF	655-643	89459-30
PRENTOX PYRONYL UL-100 CONCENTRATE	655-665	89459-31
PRENTOX ROTENONE FISH TOXICANT POWDER	655-691	89459-32
PRENTOX PBO 8	655-736	89459-33
PRENTOX PYRETHRUM EXTRACT REFINED CONCENTRATE	655-754	89459-34
PRENTOX INSECT SPRAY AND FOGGING CONCENTRATE #1	655-773	89459-35
PRENTOX 5 LB. MALATHION SPRAY	655-777	89459-36
PRENTOX PERM-X 1E	655-783	89459-37
PRENTOX FOG AND MILL SPRAY	655-784	89459-38
PRENTOX PRENBAY 1.5 EC	655-796	89459-39
PRENTOX PYRONYL 303 EMULSIFIABLE CONCENTRATE	655-797	89459-40
PRENTOX EXCITER	655-798	89459-41
PRENTOX PYRONYL 303 CONCENTRATE	655-801	89459-42
BRITTLE EXTRACT OF CUBE ROOT	655-808	89459-43
PRENTOX PERM-X UL 30-30	655-811	89459-44
PERM-X UL 31-66	655-812	89459-45
PRENTOX PERM-X UL 2-2	655-813	89459-46
PERM-X UL 4-4	655-898	89459-47
PRENTOX CFT LEGUMINE FISH TOXICANT	655-899	89459-48
PRENTOX PERM-X AQUA 20-20	655-900	89459-49
PRENTOX PERM-X AQUA 30-30	655-901	89459-50

<u>SLN Number</u>	<u>Old Registrant/ Company Number</u>	<u>New Registrant/ Company Number</u>
IL110002	655	89459
MO100004	655	89459
UT040001	655	89459
UT050003	655	89459

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after

the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee

is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated June 04, 2014 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **CENTRAL GARDEN & PET COMPANY** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,



Steve Robbins, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MS. JANELLE KAY
PYXIS REGULATORY CONSULTING, INC., AGENT FOR
PRENTISS LLC
4110 136TH STREET, NW
GIG HARBOR, WA 98332

RE: 655_RAD_89459_11_16_2014

Material Sent for Data Extraction

Reg. # 655-75

Description: Amended Under Reregistration

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 5/9/13

☐ Notification Dated _____

☒ New CSFs Dated 8/8/11

☐ Other: _____

☐ Decision #: 411738

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie A. Chao

Phone: 308-8735 Division: RD/IRB

Date: May 9, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

5-9-13

Sharon M. Johnston, Esq.
RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: Amended Reregistration Label
Product Name: Prentox 20% Pyrethrum Extract
EPA Registration Number: 655-75
EPA Decision Numbers: 411738

Dear Ms. Johnston:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Pyrethrins RED, and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

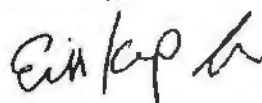
Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 8-8-2011

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: Label stamped "Accepted"
Acute Toxicity Review, dated March 28, 2011
Product Chemistry Reviews, dated October 26, 2012



20% PYRETHRUM EXTRACT

An insecticide for formulating use only.

ACTIVE INGREDIENT:

Pyrethrins.....	20.00%
OTHER INGREDIENTS**.....	80.00%
TOTAL.....	100.00%

**Contains Petroleum Distillates

PRENTOX[®] - Registered Trademark of Prentiss Incorporated

KEEP OUT OF REACH OF CHILDREN	
CAUTION	
FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye.• Call a Poison Control Center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Immediately call a Poison Control Center or doctor.• Do not induce vomiting unless told to do so by the Poison Control Center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a Poison Control Center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-222-1222 for emergency medical treatment information. You may also contact the National Pesticide Telecommunication Network at 1-800-858-7378 for information including health concerns, medical emergencies or pesticide incidents.	
NOTE TO PHYSICIAN: Contains petroleum distillate - vomiting may cause aspiration pneumonia.	
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE	

EPA Reg. No. 655-75

EPA Est. No.

NET CONTENTS _____

LOT NO. _____

Manufactured by:

PRENTISS LLC
2155 West Croft Circle
Spartanburg, SC 29302

ACCEPTED

5-9-13

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 655-75

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

User Safety Recommendations:

- User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash-waters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into insecticides for the following uses: Terrestrial Food/Feed and Non-Food Crops, Aquatic Non-Food, Greenhouse Food and Non-Food, Domestic Indoor and Outdoor, Indoor Food and Non-Food.

Not for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end-use products.

Formulated pet spray products must not contain more than 0.2% pyrethrins.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: If container is damaged: Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of wastes as below. Do not store, use, pour, or spill near heat or open flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available or reconditioning, if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Chao, Julie

From: [REDACTED]
Sent: Friday, May 03, 2013 12:59 PM
To: Chao, Julie
Subject: Re: 655-75 and 655-754: Reregistration Label Comments
Attachments: 655-75 label 05-03-2013.doc; 655-754 label 05-03-2013.doc

Julie,

Attached are the revised labels for 655-75 and 655-754.

Please let me know if you have any additional changes or comments.

Have a great weekend!

Sharon Johnston
RegGuide

In a message dated 4/22/2013 8:01:00 A.M. Central Daylight Time, Chao.Julie@epa.gov writes:

Hi Sharon,

Hope this message finds you well.

Attached are the Agency's comments on the 8-month responses for 655-75 and 655-754. Let me know if you have any questions. Otherwise, you can email me the revised labels.

Thanks,
Julie

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 22, 2013

SENT VIA EMAIL

Prentiss LLC
c/o Sharon M. Johnston, Esq.
RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: Request for Updated Reregistration Label for EPA Reg. No. 655-75
Product Name: Prentox 20% Pyrethrum Extract

Dear Ms. Johnston,

The Agency has completed a preliminary review of the label that you submitted on behalf of Prentiss LLC in support of the reregistration of EPA Reg. No. 655-75 (Prentox 20% Pyrethrum Extract), and has determined that the referenced label did not effectively incorporate all mandatory mitigation language required by the RED for products containing pyrethrins.

Within 10 working days of the date of this letter, you must submit an updated label incorporating the following mandatory mitigation language:

1. Reorder the First Aid statements as follows:

IF IN EYES
IF ON SKIN OR CLOTHING
IF SWALLOWED

Note that the First Aid statements for "If Inhaled" are optional.

2. The Hazards to Humans and Domestic Animals must be revised to read: "CAUTION. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

3. Add the following text to the label:

USER SAFETY RECOMMENDATIONS

- User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

4. Under the Directions for Use, delete the phrase "eligible for re-registration" so the statement for pet products reads, "Formulated pet spray products must not contain more than 0.2% pyrethrins."

5. Revise the "Storage" heading to read, "Pesticide Storage." Revise the "Container Disposal" heading to read, "Container Handling."

If we do not receive an amended label in response to this letter, the Agency may pursue further regulatory action, including cancellation under section 6 of FIFRA. If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,

/s/ Julie A. Chao, for

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

DATA PACKAGE BEAN SHEET

Date: 08-Mar-2013

Page 1 of 1

Decision #: 411738

DP #: (409811)

NON PRIA

Parent DP #:

Submission #: 882361

E-Sub #:

*** Registration Information ***

Registration: 655-75 - PRENTOX 20% PYRETHRUM EXTRACT

Company: 655 - PRENTISS LLC

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Moana Appleyard MAPPLEYA

Sent Date: 17-Sep-2010

PRIA Due Date: 01-Sep-2010

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (676) Product Reregistration Decision;

Ingredients: 069001, Pyrethrins (NO INERT USE)(20%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 08-Mar-2013

Due Back:

DP Ingredient: 069001, Pyrethrins (NO INERT USE)

DP Title: final reregistration for 655-75

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date:

Team Name:

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

No Efficacy uses claimed, No Companion Animal uses claimed

This pyrethrins product is recommended for final reregistration based on your review of the attached preliminary label assessment, the 40 CFR and the Pyrethrins RED. Pyrethrins products also have streamlined packages attached, which rely on the same data. In addition, efficacy and companion animal data were called in for all pyrethrins products. This product claimed no efficacy uses or companion animal uses on the label. Please contact Moana Appleyard with questions.

Date: January 16, 2013

Reg. No.: 655-75

Product Name: 20% Pyrethrum Extract

[OPPIN Name: Prentox20% Pyrethrum Extract]

PM Name/Number: Richard Gebken/10

Primary Reviewer: Jolene Trujillo

Secondary Reviewer: Mark Perry

New label or date of RD amended label: 08/19/10

Formulation Type: Formulation Intermediate

Active Ingredient Assessed: Pyrethrins/069001

Note to PM:

- The registrant has revised the storage and disposal statements to comply with PR Notice 2007-4. PRD defers the acceptability of this section to RD

Assessment can be found N:\RMIBV\label\000655/075

1) The First Aid statements must be revised to read:

IF IN EYES:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

Take off contaminated clothing.

Rinse skin immediately with plenty of water for 15-20 minutes.

Call a poison control center or doctor for treatment advice.

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

“CAUTION. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals”

3) Per the acute toxicity review the following should be added to the label:

“USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”



20% PYRETHRUM EXTRACT

An insecticide for formulating use only.

ACTIVE INGREDIENT:

Pyrethrins..... 20.00%

OTHER INGREDIENTS**..... 80.00%

TOTAL..... 100.00%

**Contains Petroleum Distillates

PRENTOX® - Registered Trademark of Prentiss Incorporated

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

If swallowed	<ul style="list-style-type: none">• Immediately call a Poison Control Center or doctor.• Do not induce vomiting unless told to do so by the Poison Control Center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye.• Call a Poison Control Center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a Poison Control Center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-222-1222 for emergency medical treatment information. You may also contact the National Pesticide Telecommunication Network at 1-800-858-7378 for information including health concerns, medical emergencies or pesticide incidents.

NOTE TO PHYSICIAN: Contains petroleum distillate - vomiting may cause aspiration pneumonia.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 655-75

EPA Est. No.

NET CONTENTS _____

LOT NO. _____

Manufactured by:

PRENTISS INCORPORATED
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapor or spray mist. Avoid contact with eyes, skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wash-waters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into insecticides for the following uses: Terrestrial Food/Feed and Non-Food Crops, Aquatic Non-Food, Greenhouse Food and Non-Food, Domestic Indoor and Outdoor, Indoor Food and Non-Food.

Not for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end-use products.

Formulated pet spray products eligible for re-registration must not contain more than 0.2% pyrethrins.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: If container is damaged. Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of wastes as below. Do not store, use, pour, or spill near heat or open flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then, offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 28, 2011

MEMORANDUM:

Subject: EPA Reg. No.: 655-75/ Prentox 20% Pyrethrum Extract
DP Barcode: 387706
Case No.: 2580

From: Santa K. Vinjamuri, Biologist *3/28/11*
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P) *MJP*

To: Moana Appleyard, CRM
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

Applicant: Prentiss, Incorporated
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

FORMULATION FROM EPA Reg. No. 655-75 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Pyrethrins :	20%
<u>Inert Ingredient(s)*</u> :	80%
Total	100%

*Contains petroleum distillates

BACKGROUND: In the 8 month response to the Pyrethrins (069001) RED, the registrant is citing data from EPA Reg. No. 73049-213 for acute toxicity studies to support the reregistration of their product, EPA Reg. No. 655-75. The MRID's: 482191-04 thru -08 (81-1, 81-2, 81-4, 81-5, 81-6) conducted by Eurofins PSL were reviewed and found to be acceptable by RMIB V on 3/3/11. The test material used in all these studies was EPA Reg. No. 73049-213. Skin Sensitization study (81-6) bearing MRID: 482191-08 self validated the subject product as Skin-Sensitizer. The Acute Inhalation study bearing MRID: 437041-01 was reviewed and found to be acceptable by TRB/RD on 7/10/98 under EPA Reg. No. 4816-17. RMIB V concurred with the RD findings while reviewing EPA Reg. No. 73049-213. The subject product is allowed to cite these studies.

RECOMMENDATIONS:

- The acute toxicity studies cited (81-1, 81-2, 81-3, 81-4, 81-5, 81-6) are acceptable to support the reregistration of EPA Reg. No. 655-75.

The acute toxicity profile for EPA Reg. No. 655-75 is currently:

Acute Oral	IV	Cited (LD ₅₀ > 5,000 mg/kg)
Acute Dermal	IV	Cited (LD ₅₀ > 5,000 mg/kg)
Acute Inhalation	IV	Cited (LC ₅₀ ≥ 2.76 mg/L)
Primary Eye	III	Cited
Primary Dermal	III	Cited (PII: 3.8)
Skin Sensitization	Skin - Sensitizer	Self validated (Cited)

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 000655-00075 **PRENTOX 20% PYRETHRUM EXTRACT**

INGREDIENT STATEMENT:

Contains petroleum distillates

SIGNAL WORD: **CAUTION**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS*:

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

*The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA, therefore, PPE has not been specified for this product.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

May pose an aspiration pneumonia hazard.

Contains petroleum distillate.

DATE OUT: 26/OCT/2012

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGA1 []; MUP [X]; EUP []
 BARCODE NO.: 406140 REG./FILE SYMBOL NO.: 655-75
 PRODUCT NAME: Prentox 20% Pyrethrum Extract
 COMPANY NAME: Prentiss, Inc. ACTION CODE: 676

FROM: Jolene Trujillo, Biologist
 Risk Management and Implementation Branch V
 Pesticide Re-evaluation Division (7508P)

Digitally signed by Jolene Trujillo
 DN: cn=Jolene Trujillo, o=USEPA,
 ou=DCSPP/OPP/PRD/RMIBV,
 email=trujillo.jolene@epa.gov,
 c=US
 Date: 2012.11.13 14:31:38 -0500

TO: Moana Appleyard, CRM
 Risk Management and Implementation Branch V
 Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

With this resubmission Prentiss, Inc. provided a revised Confidential Statement of Formula (CSF) for the basic formulation, dated 08/08/11 to support the reregistration of their product, Prentox 20% Pyrethrum Extract, EPA Reg. No. 655-75.

FINDINGS:

1. EPA Reg. No. 655-75 is a manufacturing-use product, containing the active ingredient, Pyrethrins, with a label claim nominal concentration of 20.00%. The product is for use in formulating insecticides and other products with uses accepted by EPA. The product is produced by a non-integrated system.
2. The CSF for the basic formulation has been revised as requested in the previous review (DP#387778, 06/JUL/2011). The registrant revised the values in boxes 7, 8, and 9 on the CSF to match the data reported in the study assigned MRID No. 482191-03.

The CSF is now acceptable to support reregistration of the subject product. This CSF should supersede previous CSFs for this product.

3. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3. No data are present to trigger the need for a Physical or Chemical Hazards Statement.

NOTE TO CRM: The labeling issues should be addressed during label review.

NOTE TO PM: It appears that the registrant has modified the Storage and Disposal statements to comply with PR Notice 2007-4. PRD/RMIBV defers to RD the acceptability of these statements.

CONCLUSIONS:

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 655-75.

Product Chemistry Data**Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310)****Physical and Chemical Properties**

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6315 Flammability/Flame Extension	79°C (174°F) (ERDCO Rapid Tester)	482191-03	Y
.7000 pH	3.42 at 24.3°C (1% w/v emulsion in distilled water)	482191-03	Y
.7300 Density/Relative Density	0.834 g/mL at 21.7°C	482191-03	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable;
 G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived; NR = Not required

DATE OUT: 06/JUL/2011

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP [X]; EUP []
 BARCODE NO.: D387778 REG./FILE SYMBOL NO.: 655-75
 PRODUCT NAME: Prentox 20% Pyrethrum Extract
 MRID NOS.: 481989-02, 482191-03, 482225-01, and 483295-01
 COMPANY NAME: Prentiss, Inc. ACTION CODE: 676
 CONTRACTOR: CSC PROJECT CODE: PRD-328 OPIII

FROM: Jolene Trujillo, Biologist *Jolene E. Trujillo*
 Risk Management and Implementation Branch V
 Pesticide Re-evaluation Division (7508P)

TO: Moana Appleyard, CRM
 Risk Management and Implementation Branch V
 Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case number 2580, was issued on June 7, 2006 for the Active Ingredient (AI) Pyrethrins. According to the RED, the generic data base supporting the reregistration of Pyrethrins for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Pyrethrins RED, Prentiss, Inc. provided a Confidential Statement of Formula (CSF) for the basic formulation, dated 8/13/2010; EPA Form 8570-35 (Data Matrix), dated 3/18/2011; a draft label (pin-punched 8-19-10); and two studies (MRID Nos. 481989-02 and 482225-01) to supplement cited product chemistry data. The registrant cited product chemistry data, including MRID Nos. 482191-03 and 483295-01. The registrant is requesting reregistration of their product, Prentox 20% Pyrethrum Extract, EPA Reg. No. 655-75.

FINDINGS:

1. EPA Reg. No. 655-75 is a manufacturing-use product, containing the active ingredient, Pyrethrins, with a label claim nominal concentration of 20.00%. The product is for use in formulating insecticides and other products with uses accepted by EPA. The product is produced by a non-integrated system.
2. The CSF for the basic formulation is unacceptable and must be revised as follows: The registrant must explain why the values in boxes 7, 8, and 9 on the CSF do not match the data reported in the study assigned MRID No. 482191-03 and verify which submission is correct.

Other information the CSF is acceptable. The nominal concentration of the active ingredient agrees with that on the draft label, meeting PR Notice 91-2. The certified limits for the active ingredient and inert ingredient are acceptable in accordance with 40 CFR §158.175(b)(2). All ingredients listed on the CSF are cleared for use in pesticide formulations.

3. The data reported in MRID Nos. 481989-02, 482191-03, 482225-01, and 483295-01 satisfy the product chemistry requirements under Subgroups A and B, which pertain to Product Identity, Composition, and Analysis, and Physical and Chemical Properties, respectively.

4. The Enforcement Analytical Method for the determination of active ingredient content in the product is presented in MRID Nos. 481989-02 and 483295-01. The method is adequate and satisfies the requirements under Guideline 830.1800.
- 5a. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.
- 5b. The compliance of the Physical or Chemical Hazards Statement will be determined upon receipt of revised CSF.

NOTE TO CRM: The labeling issues should be addressed during label review.

NOTE TO PM: It appears that the registrant has modified the Storage and Disposal statements to comply with PR Notice 2007-4. PRD/RMIBV defers to RD the acceptability of these statements.

CONCLUSIONS:

Except for Finding 2, the registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 655-75.

Product Chemistry Data**Subgroup A: Guideline Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)****Product Identity, Composition, and Analysis**

Guideline Reference No. (GRN) / Title 830	40 CFR §	MRID Number	Data Fulfilled
830.1550 Product Identity and Composition	158.320	481989-02, 482225-01, and CSF	Y
830.1600 Description of Materials Used to Produce the Product	158.325	481989-02, 482225-01, and CSF	Y
830.1620 Description of Production Process	158.330	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1650 Description of Formulation Process	158.335	482225-01 and CSF	Y
830.1670 Discussion of Formation of Impurities	158.340	482225-01	Y
830.1700 Preliminary Analysis	158.345	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1750 Certified Limits	158.350	481989-02 and CSF	Y
830.1800 Enforcement Analytical Method	158.355	481989-02 and 483295-01	Y

Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310)**Physical and Chemical Properties**

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Gardner No. 5 at 21.7°C	482191-03	Y
.6303 Physical State	Liquid at 21.8°C	482191-03	Y
.6304 Odor	Aromatic at 21.4°C	482191-03	Y
.6314 Oxidation/ Reduction: Chemical Incompatibility	Not tested because of the absence of an oxidizing or reducing agent.	482191-03	Y

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled														
	Not applicable. Contains no oxidizing or reducing agents.	Data Matrix	N/A														
.6315 Flammability/Flame Extension	79°C (174°F) (ERDCO Rapid Tester)	482191-03	U See Finding 2.														
.6316 Explodability	Not tested because of the absence of explosive ingredients.	482191-03	Y														
.6317 Storage Stability	<table><tr><th colspan="2">Pyrethrins</th></tr><tr><th>Time Point</th><th>Active Conc.</th></tr><tr><td>Initial</td><td>20.25%</td></tr><tr><td>3 months*</td><td>20.135%</td></tr><tr><td>6 months*</td><td>19.99%</td></tr><tr><td>9 months*</td><td>20.115%</td></tr><tr><td>12 months*</td><td>20.705%</td></tr></table> <p>*Mean concentration</p> <p>Results demonstrate stability of the <u>tested</u> <u>product</u> for 12 months at 21.091-27.075°C. No significant change in the active ingredient concentration was observed over the 12- month interval. The product was tested in steel cans with a pigmented epoxy phenolic lacquer.</p> <p>Note: Similar results were observed after storage for 12 months at 21.091- 27.075°C in amber glass bottles.</p>	Pyrethrins		Time Point	Active Conc.	Initial	20.25%	3 months*	20.135%	6 months*	19.99%	9 months*	20.115%	12 months*	20.705%	483295-01	Y
Pyrethrins																	
Time Point	Active Conc.																
Initial	20.25%																
3 months*	20.135%																
6 months*	19.99%																
9 months*	20.115%																
12 months*	20.705%																
.6319 Miscibility	Miscible with Isopar M Fluid at 25±2°C.	482191-03	Y														

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6320 Corrosion Characteristics	Results demonstrate that the <u>tested product</u> is not corrosive to its packaging after storage for 12 months at 21.091-27.075°C. The containers showed no signs of deterioration (i.e., cracking, brittleness, corrosion, leakage, or paneling). The product was tested in steel cans with a pigmented epoxy phenolic lacquer. Note: Similar results were observed after storage for 12 months at 21.091-27.075°F in amber glass bottles.	483295-01	Y
.6321 Dielectric Breakdown Voltage	Not applicable. Not for use around electrical equipment.		N/A
.7000 pH	3.42 at 24.3°C (1% w/v emulsion in distilled water)	482191-03	U See Finding 2.
.7100 Viscosity	5.98 cPs at 20°C; 3.64 cPs at 40°C	482191-03	Y
.7300 Density/Relative Density	0.834 g/mL at 21.7°C	482191-03	U See Finding 2.

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived; NR = Not required

Personal privacy information



To: [REDACTED]
Cc: [REDACTED]
Bcc: [REDACTED]
Subject: Pyrethrins products for Prentiss
From: Moana Appleyard/DC/USEPA/US - Wednesday 10/17/2012 01:21 PM

Hi Sharon,

We are trying to finish up the pyrethrins product reregistration and I have a few Prentiss products that have minor issues:

655-75: Needs revised CSF per review dated July 6, 2011

655-754: Needs revised CSF, boxes 7 and 8 need to match the parent product (7.5-7.9 and $>61^{\circ}\text{C}$, respectively)

If you could send me the revised CSFs within a week, that would be great.

Thanks,
Moana

Moana Appleyard
Chemical Review Manager
Pesticide Re-evaluation Division
OPP/PRD/RMIBV
(703) 308-8175

appleyard.moana@epa.gov



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 655-75	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Prentox 20% Pyrethrum Extract	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - 8-month response to pyrethrins PDCI

e-mail: Johnston@RegGuide.net

fax: (636) 948-9720

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 - 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sharon M. Johnston		Title Agent for Prentiss, Inc.	
		Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Data Application Received (Stamped)
2. Signature 		3. Title Agent for Prentiss, Inc.	
4. Typed Name Sharon M. Johnston		5. Date August 13, 2010	



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

EPA File Symbol/Registration Number

655-75

Product Name

Prentox 20% Pyrethrum Extract

Date of Confidential Statement of Formula (EPA Form 8570-4)

August 13, 2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Pyrethrins

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Pyrethrins		
Product ingredient source information may be entitled to confidential treatment		
*Used to formulate 655-754		
Signature	Name and Title Sharon M. Johnston / Regulatory Consultant	Date August 13, 2010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Prentiss, Inc., 3600 Mansell Road, Suite 350, Alpharetta, GA 30022 TEL: 636-942-2583	EPA Registration Number/File Symbol 655-75
Active Ingredient(s) and/or representative test compound(s) Pyrethrins	Date August 13, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food & Non-Food, Greenhouse Food & Non-Food, Domestic Outdoor, Indoor	Product Name Prentox 20% Pyrethrum Extract

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☒ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

August 13, 2010

Typed or Printed Name and Title

Sharon M. Johnston / Regulatory Consultant




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 18, 2011		EPA Reg. No./File Symbol: 655-75		Page 1 of 3	
Applicant's/Registrant's Name & Address: Preniss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022		Product: Prenlox 20% Pyrethrum Extract			
Ingredient: Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830-1550	Chemical Identity	48222501	Preniss, Inc.	OWN	
61-2/830-1600 & 1650	Beginning Materials & Manufacturing Process	48222501	Preniss, Inc.	OWN	
61-3/830-1670	Discussion of Formation of Impurities	48222501	Preniss, Inc.	OWN	
62-1/830-1700	Preliminary Analysis				NO INITIAL SUBMITTAL DATE
62-2/830-1750	Certification of Ingredients Limits	48198902	Preniss, Inc.	OWN	
62-3/830-1800	Analytical Method to Verify Certified Limits	48198902	Preniss, Inc.	OWN	
63-2/830-6302	Color	48219103	Valent BioSciences Corporation	PER	
63-3/830-6303	Physical State	48219103	Valent BioSciences Corporation	PER	
63-4/830-6304	Odor	48219103	Valent BioSciences Corporation	PER	
63-5/830-7200	Melting Point				NA - MUP
63-6/830-7220	Boiling Point				NA - MUP
63-7/830-7300	Density, Bulk Density or Specific Gravity	48219103	Valent BioSciences Corporation	PER	
63-8/830-7840 & 830-7860	Solubility				NA - MUP
63-9/830-7950	Vapor Pressure				NA - MUP
63-10/830-7370	Dissociation Constant				NA - MUP
Signature: 			Name and Title: Sharon M. Johnston Regulatory Consultant		Date: 03-18-2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 18, 2011		EPA Reg No./File Symbol 655-75		Page 2 of 3	
Applicant's/Registrant's Name & Address Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022		Product Prentox 20% Pyrethrum Extract			
Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - MUP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - MUP
63-14/830.6314	Oxidizing/Reducing Action				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	48219103	Valent BioSciences Corporation	PER	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	48329501	Valent BioSciences Corporation	PER	
63-18/830.7100	Viscosity	48219103	Valent BioSciences Corporation	PER	
63-19/830.6319	Miscibility				NA - Not an EC
63-20/830.6320	Corrosion Characteristics	48329501	Valent BioSciences Corporation	PER	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	48219104	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	48219105	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43704101	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	48219106	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-18-2011

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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 18, 2011


EPA Reg No./File Symbol 655-75

Page 3 of 3

Applicant's/Registrant's Name & Address	Pientiss, Inc 3600 Munsell Road, Suite 350 Alpharetta, GA 30022
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Product	Prenox 20% Pyrethrum Extract
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Ingredient Pyrethrins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-51870.2500	Primary Dermal Irritation	48219107	Valent BioSciences Corporation	PER	
81-51870.2500	Dermal Sensitization	48219108	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-18-2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CERTIFIED MAIL

Ms. Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: Product Chemistry Deficiencies for Pyrethrins Products, EPA Reg. Nos. 655-52, -75, -128, -471, -773, -784

Dear Ms. Johnston:

The enclosed review indicates deficiencies that must be corrected in order to satisfy the product chemistry requirements for product reregistration:

1. EPA Reg. No. 655-52: Review dated July 8, 2011 by Nina Simeonova
2. EPA Reg. No. 655-75: Review dated July 6, 2011 by Jolene Trujillo
3. EPA Reg. No. 655-128: Review dated July 13, 2011 by Nina Simeonova
4. EPA Reg. No. 655-471: Review dated July 7, 2011 by Nina Simeonova
5. EPA Reg. No. 655-773: Review dated July 5, 2011 by Nina Simeonova
6. EPA Reg. No. 655-784: Review dated July 14, 2011 by Nina Simeonova

Please submit the required information within 10 days from the receipt of this letter. Failure to comply within this timeframe will result in a Notice of Intent to Suspend your Pyrethrins product registrations. Please contact me at (703) 308-8175 if you have questions.

Sincerely,

Moana R. Appleyard
Chemical Review Manager
Risk Management Implementation Branch V
Pesticide Re-evaluation Division

Enclosures



870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048 - 800-323-9597

August 10, 2010

Pesticide Re-evaluation Division (PRD)
Office of Pesticide Programs (7508P)
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

ATTN: Barbara Briscoe, Chemical Review Manager – Pyrethrins (Case# 2580)
Julia Stokes, Chemical Review Manager – Piperonyl Butoxide (Case# 2525)

SUBJECT: **Letter of Authorization**
Prentiss, Inc.
Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Dear Ms. Briscoe/Stokes:

Valent BioSciences Corporation (VBC) of Libertyville, Illinois, authorizes the US Environmental Protection Agency to review all data and information on file for Purified Pyrethrum Extract 20% (EPA Reg. No. 73049-213) to support the re-registration of the above-subject product by Prentiss, Inc.

These data include (but are not limited to) the following study volumes:

<u>Study Type</u>	<u>MRID No.</u>
Physical & Chemical Properties	To be submitted by VBC under 73049-213
Storage Stability & Corrosion Characteristics	To be submitted by VBC under 73049-213
Acute Oral Toxicity	To be submitted by VBC under 73049-213
Acute Dermal Toxicity	To be submitted by VBC under 73049-213
Acute Inhalation Toxicity	43704101
Primary Eye Irritation	To be submitted by VBC under 73049-213
Primary Skin Irritation	To be submitted by VBC under 73049-213
Dermal Seositization	To be submitted by VBC under 73049-213

This authorization letter is qualified to the extent that: (1) the applicant or any other person, except the Agency, shall not have access to said data unless specifically authorized in writing by Valent BioSciences Corporation, or when in the opinion of your Agency, it is required in judicial or administrative proceedings; (2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application; and, (3) this authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Valent BioSciences Corporation, and (4) this authorization shall expire on August 10, 2012. Further use of the data will require authorization by Valent BioSciences Corporation.



870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048 - 800-323-9597

Briscoe/Stokes
August 10, 2010
Page 2

Please contact me at (847) 968-4844 if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "NASSAF".

Nasser Assaf, Ph.D.
Manager, Product Safety & Regulatory Affairs

cc: Sharon Johnston; Agent for Prentiss
VBC Regulatory Customer File



870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048 - 800-323-9597

August 10, 2010

Pesticide Re-evaluation Division (PRD)
Office of Pesticide Programs (7508P)
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

ATTN: Barbara Briscoe, Chemical Review Manager – Pyrethrins (Case# 2580)
Julia Stokes, Chemical Review Manager – Piperonyl Butoxide (Case# 2525)

SUBJECT: **Letter of Authorization**
Prentiss, Inc.
Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Dear Ms. Briscoe/Stokes:

Valent BioSciences Corporation (VBC) of Libertyville, Illinois, authorizes the US Environmental Protection Agency to review all data and information on file for Purified Pyrethrum Extract 20% (EPA Reg. No. 73049-213) to support the re-registration of the above-subject product by Prentiss, Inc.

These data include (but are not limited to) the following study volumes:

<u>Study Type</u>	<u>MRID No.</u>
Physical & Chemical Properties	To be submitted by VBC under 73049-213
Storage Stability & Corrosion Characteristics	To be submitted by VBC under 73049-213
Acute Oral Toxicity	To be submitted by VBC under 73049-213
Acute Dermal Toxicity	To be submitted by VBC under 73049-213
Acute Inhalation Toxicity	43704101
Primary Eye Irritation	To be submitted by VBC under 73049-213
Primary Skin Irritation	To be submitted by VBC under 73049-213
Dermal Sensitization	To be submitted by VBC under 73049-213

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 13, 2010			EPA Reg No./File Symbol 655-75		Page 1 of 3
Applicant's/Registrant's Name & Address Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022			Product Prentox 20% Pyrethrum Extract		
Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-2/830.1600 & 1650	Beginning Materials & Manufacturing Process	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-3/830.1670	Discussion of Formation of Impurities	Vol. 1 of 2	Prentiss, Inc.	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
61-2/830.1750	Certification of Ingredients Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
61-3/830.1800	Analytical Method to Verify Certified Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
63-2/830.6302	Color	73049-213	Valent BioSciences Corporation	PER	
63-3/830.6303	Physical State	73049-213	Valent BioSciences Corporation	PER	
63-4/830.6304	Odor	73049-213	Valent BioSciences Corporation	PER	
63-5/830.7200	Melting Point				NA - MUP
63-6/830.7220	Boiling Point				NA - MJP
63-7/830.7300	Density, Bulk Density or Specific Gravity	73049-213	Valent BioSciences Corporation	PER	
63-8/830.7840 & 830.7860	Solubility				NA - MUP
63-9/830.7950	Vapor Pressure				NA - MUP
63-10/830.7370	Dissociation Constant				NA - MUP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 08-13-2010



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Applicant's/Registrant's Name & Address Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022		Product Prentox 20% Pyrethrum Extract			
Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - MUP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - MUP
63-14/830.6314	Oxidizing/Reducing Action				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	73049-213	Valent BioSciences Corporation	PER	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6717	Storage Stability	73049-213	Valent BioSciences Corporation	PER	
63-18/830.7100	Viscosity	73049-213	Valent BioSciences Corporation	PER	
63-19/830.6319	Miscibility				NA - Not an EC
63-20/830.6320	Corrosion Characteristics	73049-213	Valent BioSciences Corporation	PER	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43704101	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	73049-213	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 08-13-2010

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DATA MATRIX

Date August 13, 2010

EPA Reg No./File Symbol 655-75

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Applicant's/Registrant's Name & Address	Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022
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Product	Prentox 20% Pyrethrum Extract
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Ingredient	Pyrethrins
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[illegible]

Signature

Name and Title	Sharon M. Johnston Regulatory Consultant
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Date
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Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-2/830.1600 & 1650	Beginning Materials & Manufacturing Process	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-3/830.1670	Discussion of Formation of Impurities	Vol. 1 of 2	Prentiss, Inc.	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
61-2/830.1750	Certification of Ingredients Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
61-3/830.1800	Analytical Method to Verify Certified Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
63-2/830.6302	Color	73049-213	Valent BioSciences Corporation	PER	
63-3/830.6303	Physical State	73049-213	Valent BioSciences Corporation	PER	
63-4/830.6304	Odor	73049-213	Valent BioSciences Corporation	PER	
63-5/830.7200	Melting Point				NA - MUP
63-6/830.7220	Boiling Point				NA - MJP
63-7/830.7300	Density, Bulk Density or Specific Gravity	73049-213	Valent BioSciences Corporation	PER	
63-8/830.7840 & 830.7860	Solubility				NA - MUP
63-9/830.7950	Vapor Pressure				NA -MUP
63-10/830.7370	Dissociation Constant				NA - MUP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 08-13-2010

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Applicant's/Registrant's Name & Address Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022		Product Prentox 20% Pyrethrum Extract			
Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - MUP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - MUP
63-14/830.6314	Oxidizing/Reducing Action				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	73049-213	Valent BioSciences Corporation	PER	
63-16/830.6316	Explodability				NA - not potentially explosive
63-17/830.6717	Storage Stability	73049-213	Valent BioSciences Corporation	PER	
63-18/830.7100	Viscosity	73049-213	Valent BioSciences Corporation	PER	
63-19/830.6319	Miscibility				NA - Not an EC
63-20/830.6320	Corrosion Characteristics	73049-213	Valent BioSciences Corporation	PER	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43704101	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	73049-213	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 08-13-2010

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Date August 13, 2010		EPA Reg No./File Symbol 655-75	Page 3 of 3
Applicant's/Registrant's Name & Address	Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022	Product Prentox 20% Pyrethrum Extract	

[illegible]

Signature	Name and Title	Date
	Sharon M. Johnston Regulatory Consultant	08-13-2010



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Date August 13, 2010	EPA Reg No./File Symbol 655-75	Page 1 of 3
Applicant's/Registrant's Name & Address Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022	Product Prentox 20% Pyrethrum Extract	

Ingredient Pyrethrins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-2/830.1600 & 1650	Beginning Materials & Manufacturing Process	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-3/830.1670	Discussion of Formation of Impurities	Vol. 1 of 2	Prentiss, Inc.	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
61-2/830.1750	Certification of Ingredients Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
61-3/830.1800	Analytical Method to Verify Certified Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
63-2/830.6302	Color	73049-213	Valent BioSciences Corporation	PER	
63-3/830.6303	Physical State	73049-213	Valent BioSciences Corporation	PER	
63-4/830.6304	Odor	73049-213	Valent BioSciences Corporation	PER	
63-5/830.7200	Melting Point				NA - MUP
63-6/830.7220	Boiling Point				NA - MJP
63-7/830.7300	Density, Bulk Density or Specific Gravity	73049-213	Valent BioSciences Corporation	PER	
63-8/830.7840 & 830.7860	Solubility				NA - MUP
63-9/830.7950	Vapor Pressure				NA - MUP
63-10/830.7370	Dissociation Constant				NA - MUP

Signature

Name and Title Sharon M. Johnston
Regulatory Consultant

Date
08-13-2010



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DATA MATRIX

Date August 13, 2010

EPA Reg No./File Symbol 655-75

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Applicant's/Registrant's Name & Address
Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

Product
Prentox 20% Pyrethrum Extract

Ingredient Pyrethrins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - MUP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - MUP
63-14/830.6314	Oxidizing/Reducing Action				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	73049-213	Valent BioSciences Corporation	PER	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6717	Storage Stability	73049-213	Valent BioSciences Corporation	PER	
63-18/830.7100	Viscosity	73049-213	Valent BioSciences Corporation	PER	
63-19/830.6319	Miscibility				NA - Not an EC
63-20/830.6320	Corrosion Characteristics	73049-213	Valent BioSciences Corporation	PER	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43704101	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	73049-213	Valent BioSciences Corporation	PER	

Signature

Name and Title
Sharon M. Johnston
Regulatory Consultant

Date
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Applicant's/Registrant's Name & Address
Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

Product
Prentox 20% Pyrethrum Extract

Ingredient Pyrethrins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-5/870.2500	Primary Dermal Irritation	73049-213	Valent BioSciences Corporation	PER	
81-6/870.2600	Dermal Sensitization	73049-213	Valent BioSciences Corporation	PER	

Signature

Name and Title
Sharon M. Johnston
Regulatory Consultant

Date
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Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-2/830.1600 & 1650	Beginning Materials & Manufacturing Process	Vol. 1 of 2	Prentiss, Inc.	OWN	
61-3/830.1670	Discussion of Formation of Impurities	Vol. 1 of 2	Prentiss, Inc.	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
61-2/830.1750	Certification of Ingredients Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
61-3/830.1800	Analytical Method to Verify Certified Limits	Vol. 2 of 2	Prentiss, Inc.	OWN	
63-2/830.6302	Color	73049-213	Valent BioSciences Corporation	PER	
63-3/830.6303	Physical State	73049-213	Valent BioSciences Corporation	PER	
63-4/830.6304	Odor	73049-213	Valent BioSciences Corporation	PER	
63-5/830.7200	Melting Point				NA - MUP
63-6/830.7220	Boiling Point				NA - MJP
63-7/830.7300	Density, Bulk Density or Specific Gravity	73049-213	Valent BioSciences Corporation	PER	
63-8/830.7840 & 830.7860	Solubility				NA - MUP
63-9/830.7950	Vapor Pressure				NA - MUP
63-10/830.7370	Dissociation Constant				NA - MUP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 08-13-2010



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DATA MATRIX

Date August 13, 2010

EPA Reg No./File Symbol 655-75

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Applicant's/Registrant's Name & Address
Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

Product
Prentox 20% Pyrethrum Extract

Ingredient Pyrethrins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - MUP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - MUP
63-14/830.6314	Oxidizing/Reducing Action				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	73049-213	Valent BioSciences Corporation	PER	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6717	Storage Stability	73049-213	Valent BioSciences Corporation	PER	
63-18/830.7100	Viscosity	73049-213	Valent BioSciences Corporation	PER	
63-19/830.6319	Miscibility				NA - Not an EC
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81-2/870.1200	Acute Dermal Toxicity	73049-213	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43704101	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	73049-213	Valent BioSciences Corporation	PER	

Signature

Name and Title
Sharon M. Johnston
Regulatory Consultant

Date
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DATA MATRIX

Date August 13, 2010			EPA Reg No./File Symbol 655-75		Page 3 of 3
Applicant's/Registrant's Name & Address Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022			Product Prentox 20% Pyrethrum Extract		
Ingredient Pyrethrins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-5/870.2500	Primary Dermal Irritation	73049-213	Valent BioSciences Corporation	PER	
81-6/870.2600	Dermal Sensitization	73049-213	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 08-13-2010

RegGuide

August 13, 2010

Document Processing Desk (PRD/DCI)
Pesticide Re-evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Barbara Briscoe
Chemical Review Manager
Pyrethrins; Case No. 2580; PDCI-069001-26530

SUBJECT: **Pyrethrins** – 8-Month Response to Data Call-In Notice
Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Dear Ms. Briscoe:


Enclosed, please find the 8-month response to the Pyrethrins data call-in notice for the above-subject product.

The following materials are enclosed:

- 1) Application for Registration
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Letter of Authorization from Valent BioSciences Corporation
- 6) Data Matrix
- 7) Draft Labeling (5 copies)
- 8) Data Volumes 1 – 2 (3 copies)

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.

Enclosures

cc: Larry Eichler; Prentiss

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-Registration

Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

3. Transmittal Date

August 13, 2010

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<u>Reject (01)</u>	1 of 2	830.1550, 1600, 1650 & 1670	Product Identity and Composition of Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75
<u>48198902</u>	2 of 2	830.1700, 1750 & 1800	Analysis and Certification of Product Ingredients of Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Company Official: Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.

Phone: (636) 942-2583

Signature:  _____

Pyrethroids
655-75

Memorandum

8-30-10
JH

Date: 8 / 27 / 10

To: RMIBV BB, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☐ fully accepted submission
☒ partially accepted submission
☐ rejected submission



August 27, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRENTISS, INC.
3600 MANSELL ROAD, SUITE 350
ALPHARETTA, GA 30022-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 19-AUG-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [01]:

* The following page(s) in this study is/are illegible due to the poor quality of the photocopying: 12.

RegGuide

August 13, 2010

Document Processing Desk (PRD/DCI)
Pesticide Re-evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Barbara Briscoe
Chemical Review Manager
Pyrethrins; Case No. 2580; PDCI-069001-26530

SUBJECT: **Pyrethrins** – 8-Month Response to Data Call-In Notice
Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Dear Ms. Briscoe:

Enclosed, please find the 8-month response to the Pyrethrins data call-in notice for the above-subject product.

The following materials are enclosed:

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- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Letter of Authorization from Valent BioSciences Corporation
- 6) Data Matrix
- 7) Draft Labeling (5 copies)
- 8) Data Volumes 1 – 2 (3 copies)

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.

Enclosures

cc: Larry Eichler; Prentiss

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-Registration

Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

3. Transmittal Date

August 13, 2010

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<u>Reject (01)</u>	1 of 2	830.1550, 1600, 1650 & 1670	Product Identity and Composition of Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75
<u>48198902</u>	2 of 2	830.1700, 1750 & 1800	Analysis and Certification of Product Ingredients of Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Company Official: Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.

Phone: (636) 942-2583

Signature: 



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 17, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRENTISS, INC.
3600 MANSELL ROAD, SUITE 350
ALPHARETTA, GA 30022-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-SEP-2010. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

RegGuide

August 13, 2010

Document Processing Desk (PRD/DCI)
Pesticide Re-evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Barbara Briscoe
Chemical Review Manager
Pyrethrins, Case No. 2580; PDCI-069001-26530

SUBJECT: **Pyrethrins** – 8-Month Response to Data Call-In Notice
Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Dear Ms. Briscoe:

Enclosed, please find the 8-month response to the Pyrethrins data call-in notice for the above-subject product.

The following materials are enclosed:

- 1) Application for Registration
- 2) Formulator's Exemption Statement
- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Letter of Authorization from Valent BioSciences Corporation
- 6) Data Matrix
- 7) Draft Labeling (5 copies)
- 8) Data Volumes 1 – 2 (3 copies)

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.

Enclosures

cc: Larry Eichler, Prentiss

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-Registration

Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

3. Transmittal Date

August 13, 2010

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<u>48222501</u>	1 of 2	830.1550, 1600, 1650 & 1670	Product Identity and Composition of Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75
<u>48198902</u>	2 of 2	830.1700, 1750 & 1800	Analysis and Certification of Product Ingredients of Prentox 20% Pyrethrum Extract; EPA Reg. No. 655-75

Company Official: Sharon M. Johnston
Regulatory Consultant
Agent for Prentiss, Inc.

Phone: (636) 942-2583

Signature: 

Personal privacy information



Re: Pyrethrins products for Prentiss

[REDACTED]

to:

Moana Appleyard

10/17/2012 04:00 PM

Hide Details

From:

[REDACTED]

To: Moana Appleyard/DC/USEPA/US@EPA

1 Attachment



655-75 CSF 08-08-2011.pdf

Moana,

Attached is the CSF corrected in August, 2011. I guess you did not receive it?

As for the 655-754, I did not get a product chemistry review for this one. So if the changes you noted are the only ones, I'll make those tweaks and get it right to you.

Sharon Johnston
RegGuide

In a message dated 10/17/2012 12:35:22 P.M. Central Daylight Time, Appleyard.Moana@epamail.epa.gov writes:

Hi Sharon,
We are trying to finish up the pyrethrins product reregistration and I have a few Prentiss products that have minor issues:

655-75: Needs revised CSF per review dated July 6, 2011

655-754: Needs revised CSF, boxes 7 and 8 need to match the parent product (7.5-7.9 and >61°C, respectively)

If you could send me the revised CSFs within a week, that would be great.

Thanks,
Moana

Moana Appleyard
Chemical Review Manager
Pesticide Re-evaluation Division
OPP/PRD/RMIBV
(703) 308-8175

appleyard.moana@epa.gov

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address PRENTISS INC C.B. 2000 FLORAL PARK, NY 110012000	2. Case # and Name 2580 Pyrethrin, and derivs. EPA Reg. No. 655-75	3. Date and Type of DCI and Number 21-May-2009 PRODUCT SPECIFIC ID # PDCI-069001-26530
---	--	---

4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.1550	<u>Product Chemistry Data Requirements (Conventional Chemical)</u> Product Identity and composition (41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	1
830.1600	Description of materials used to produce the product (42)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	1
830.1620	Description of production process (44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI	8	8
830.1650	Description of formulation process (45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	1
830.1670	Discussion of formation of impurities (46)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	1
830.1700	Preliminary analysis (1, 2, 43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI	8	8
830.1750	Certified limits (47)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	1

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law

Signature and Title of Company's Authorized Representative

[Signature] Regulatory Consultant

11. Date

10-08-09

12. Name of Company Prentiss, Inc.

13. Phone Number 636-942-2583

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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4. Guideline Requirement or	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.1800	Enforcement analytical method (48)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	1
830.6302	Color (9)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	3
830.6303	Physical state (11)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	3
830.6304	Odor (12)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	3
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions (3, 4, 49)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI	8	8
830.6314	Oxidizing or reducing action (5)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	8
830.6315	Flammability (6)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	3
830.6316	Explosibility (7)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	8
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date 10-08-09 97		

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.6317	Storage stability of product (50)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	16	3
830.6319	Miscibility (8)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	8
830.6320	Corrosion characteristics (52)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	16	3
830.6321	Dielectric breakdown voltage (10)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	8
830.7000	pH of water solutions or suspensions (17,18)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	8
830.7050	UV/Visible absorption					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/PAI	8	8
830.7100	Viscosity (19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	MP/EP	8	3
830.7200	Melting point/melting range (20,21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI	8	8
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date	10-08-09	

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
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Use additional sheet(s) if necessary.

1. Company Name and Address PRENTISS INC C.B. 2000 FLORAL PARK, NY 110012000		2. Case # and Name 2580 Pyrethrin, and derivs. EPA Reg. No. 655-75		3. Date and Type of DCI and Number 21-May-2009 PRODUCT SPECIFIC ID # PDCI-069001-26530					
4. Guideline Requirement	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7220	Boiling point/boiling range (22,23)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI	8	8
830.7300	Density/relative density (24,25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/MP/EP	8	3
830.7370	Dissociation constant in water (13,14)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI or PAI	8	8
830.7550	Partition coefficient (n-octanol/water), shake flask method (15)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/PAI	8	8
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography (16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI/PAI	8	8
830.7840	Water solubility: Column elution method, shake flask method (26)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI or PAI	8	8
830.7860	Water solubility, generator column method (27)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI or PAI	8	8
830.7950	Vapor pressure (28,29)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI or PAI	8	8
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date 10-08-09	99	

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address PRENTISS INC C.B. 2000 FLORAL PARK, NY 110012000		2. Case # and Name 2580 Pyrethrin, and derivs. EPA Reg. No. 655-75			3. Date and Type of DCI and Number 21-May-2009 PRODUCT SPECIFIC ID # PDCI-069001-26530					
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response	
			1	2	3					
	Toxicology Data Requirements (Conventional Chemical)									
870.1100	Acute Oral Toxicity (33 ,40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI,EP,dilute EP?	8	3	
870.1200	Acute dermal toxicity (30 ,31 ,51)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI,EP,dilute EP?	8	3	
870.1300	Acute inhalation toxicity (32)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI & EP	8	6	
870.2400	Acute eye irritation (34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI & EP	8	3	
870.2500	Acute dermal irritation (35 ,36)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI & EP	8	3	
870.2600	Skin sensitization (37 ,38)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	TGAI & EP	8	3	
870.7200	Companion animal safety (57)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	EP	8	8	
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date	10-08-09		

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

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4. Guideline Requirement	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
B10.3100	Soil treatments for imported fire ants (53)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	EP	8	8
B10.3200	Livestock, poultry, fur- and wool-bearing animal treatments (54)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	EP	8	8
B10.3300	Treatments to control pests of humans and pets (39)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	EP	8	8
B10.3400	Mosquito, black fly, and biting midge (sand fly) treatments (55)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	EP	8	8
B10.3500	Premises treatments (56)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T	EP	8	8
SS-1	Special Study For Arthropods (58)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T		8	8

Initial to indicate certification as to information on this page
(full text of certification is on page one).

Date

10-08-09

101



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Sharon M. Johnston
Prentiss, Inc.
3600 Mansell Road, Suite 350
Alpharetta, GA 30022

100 1822

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Ms. Johnson:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated January 25, 2011 for the following product(s):

Prentox 20% Pyrethrum
Extract

Reg. No. 655-75

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken", is written over a horizontal line.

Richard J. Gebken
Product Manager
Insecticide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 655-75	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Prentox 20% Pyrethrum Extract	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Prentiss, Inc. 3600 Mansell Road, Suite 350 Alpharetta, GA 30022 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>FEB 18 2011</u> Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR Sections 156.10, 156.140, 156.144, 156.146 and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR Sections 156.10, 156.140, 156.144, 156.146 and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 30 & 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sharon M. Johnston		Title Agent for Prentiss, Inc.	
		Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Data Application Received (Stamped)
2. Signature 		3. Title Agent for Prentiss, Inc.	
4. Typed Name Sharon M. Johnston		5. Date January 25, 2011	



20% PYRETHRUM EXTRACT

An insecticide for formulating use only.

ACTIVE INGREDIENT:

Pyrethrins.....20.00%

OTHER INGREDIENTS*:.....80.00%

TOTAL.....100.00%

*Contains Petroleum Distillates

PRENTOX® - Registered Trademark of Prentiss Incorporated

NOTICE

FEB 18 2011

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

Have the product container or label with you when calling a poison control center or physician, or going for treatment.

If swallowed	<ul style="list-style-type: none">• Immediately call a Poison Control Center, physician, or the National Pesticide Information Center at 1-800-858-7378.• Do not induce vomiting unless told to do so by the Poison Control Center or physician.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious or convulsing person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center, physician, or the National Pesticide Information Center at 1-800-858-7378 for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue to rinse eye.• Call a Poison Control Center, physician, or the National Pesticide Information Center at 1-800-858-7378 for treatment advice.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a Poison Control Center, physician, or the National Pesticide Information Center at 1-800-858-7378 for treatment advice.

NOTE TO PHYSICIAN: Contains petroleum distillate – vomiting may cause aspiration pneumonia.

For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 655-75

EPA Est. No.

NET CONTENTS _____

LOT NO. _____

Manufactured by:

PRENTISS INCORPORATED
Plant: Kaolin Road, Sandersville, GA 31082
Office: 3600 Mansell Road, Suite 350, Alpharetta, GA 30022

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed. Keep out of reach of children. Avoid breathing spray mist. Avoid skin and eye contact. Wash thoroughly after handling and before eating or smoking.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and other wildlife. Do not apply directly to water. Do not contaminate water by disposal of wastes. Apply this product only as specified on this label. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL HAZARDS

Do not use, or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

NOTE TO FORMULATORS

Formulators who use this product are responsible for providing data to support Registration. For further information on the properties of this product, see our Product Information Sheet.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

STORAGE: If container is damaged: Stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent contact with the product or its vapors. Cover the spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand, or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of wastes as below. Do not store, use, pour, or spill near heat or open flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: ~~Non-refillable container. Do not reuse or refill this container. Triple-rinse (or equivalent). Then, Offer for recycling, if available or reconditioning, if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.~~

